Endo Menu

Service Manual

Welch Allyn®

VideoPath® VC-200

VideoColonoscope

Operating Manual

Thank you for your purchase of a Welch Allyn Flexible VideoColonoscope. The operating and maintenance instructions found in this manual should be followed to ensure many years of reliable service. Please read these instructions thoroughly before attempting to use your new Flexible VideoColonoscope.

WARNING: The user of this equipment should be thoroughly trained in the medical procedures appropriate to the equipment. Furthermore, time should be taken to read and understand these instructions before performing any procedures. Instructions for other equipment used in conjunction with any VideoEndoscope (e.g., suction machines) should also be read and understood. Failure to do so may result in injury to the patient and/or damage to the instrument.

While this manual describes the recommended protocol for inspecting and operating the equipment, it does not outline procedural techniques. Only physicians trained and versed in flexible endoscopy should use this equipment.

CAUTION: Federal (USA) law restricts this device to sale by/to or on the order of a physician or other appropriately licensed medical professional.

Infection Control Note

This manual includes a current list of disinfecting and sterilizing solutions and processes. However, since infection control procedures involve complex and controversial issues and are constantly changing, it is recommended that the users of this equipment keep informed of the latest information and regulations pertaining to infection control.

CE

The CE mark on this device indicates it has been tested to and conforms with the provisions noted within the 93/42/EEC Medical Devices Directive.

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Conventions

WARNING: alerts the user to possible serious injury, death or other adverse reaction associated with the use or misuse of the device.

CAUTION: indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It also alerts against unsafe practices.

NOTE: provides supplemental information to the text and indicates a potentially hazardous situation, which, if not avoided, may result in property damage. Additionally, it highlights important information on the use of this equipment.

The Welch Allyn 31500 Colonoscope is intended to be used in facilitating colonoscopy procedures.

Specifications

Parameter	Colonoscope (31500)
Angle of View	145°
Depth of View	5-100mm
Tip Deflection	Up: 180° Down: 180° Right: 160° Left: 160°
Distal Rigid Diameter	∅13.4mm
Insertion Tube Diameter	∅12.8mm
Diameter of Accessory/ Suction Channel	∅3.8mm
Insertion Tube Working Length	1700mm
Total Length	2020mm

Parameter	Colonoscope (31500)
Function Controls- Communication version	Freeze, Copy, Video Lockable Steering Brakes
Environment	
Operating	+10°C (50°F) to +40°C (104°F) 30 - 75% R.H. 700 hPa - 1060 hPa Altitude
Transport/Storage	-20°C to +49°C 95% R.H. Max. 700 hPa - 1060 hPa Altitude
Operating Mode	Continuous
Compliance	UL 2601-1, IEC 60601-1, IEC 60601-2-18, CAN/CSA C22.2 No. 601.1, EN 60601-1-2, CE

NOTE: This device complies with current required standards for electromagnetic interference and should not present problems to other equipment or be affected by other devices. As a precaution, avoid using this device in close proximity to other equipment.

Symbols

Type BF **IPX7** Protected against the effects of immersion

Warnings

WARNING: Total system risk current should not exceed 50µA. An isolation transformer is required if the total system risk current exceeds 50µA when accessories are interconnected.

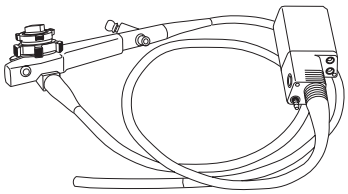
WARNING: If the endoscope is removed from the light source, the lamps will remain lit. DO NOT look directly into the lights. The intensity of the illumination may damage your eyes. If the instrument is removed from the light source, either turn off the main power switch or press the Lamp Ignition/Standby switch to turn off the lamps and put them in a standby mode.

WARNING: High energy radiated light may be transmitted from the light emission window of the endoscope, giving rise to high temperatures in front of the light emission window. To minimize hazards, avoid prolonged exposure or contact.

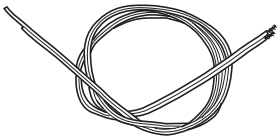
WARNING: DO NOT use this equipment in the presence of any flammable anesthetics.

Components

Flexible VideoColonoscope Set Includes:



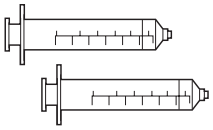
31500 Flexible VideoColonoscope



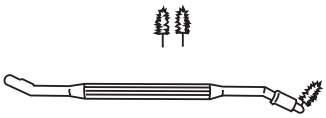
31020 Channel Cleaning Brush (2 each)

31021 Valve Reprocessing Caps

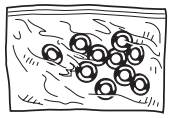
31039 (Biopsy Seals) Procedure Scope



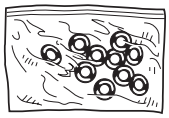
31023 60cc Syringes (2 each)



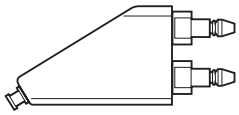
33924 Air/Water Nozzle Cleaning Brush



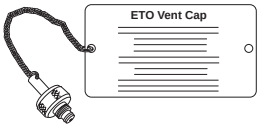
31024 Air/Water Valve “O” Ring Kit



31025 Suction Valve “O” Ring Kit



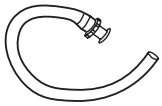
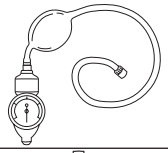
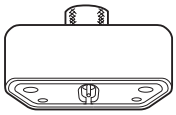
31027 Air/Water Reprocessing Adapter



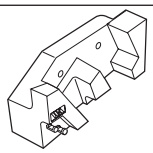
31029 Shipping/ETO Vent Cap

31030 Distal Reprocessing Cap (6 each)

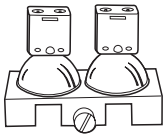
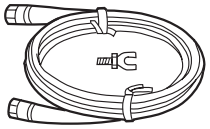
Components (continued)

	**31038**	Suction Reprocessing Adapter
	31031	Valve Well Cleaning Brush
	**31037**	Leakage Tester
	33918	Valve Lubricant
	**31028**	Soaking Cap

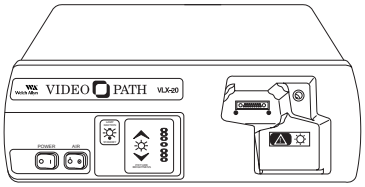
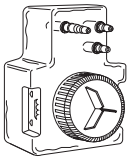
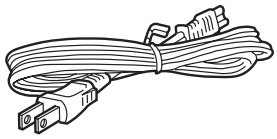
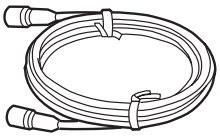
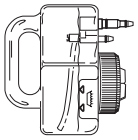
Optional Accessories (not included in set):

	31032	Air/Water Valve
	31033	Suction Valve
	**31035**	Instrument Hanger

Components (continued)

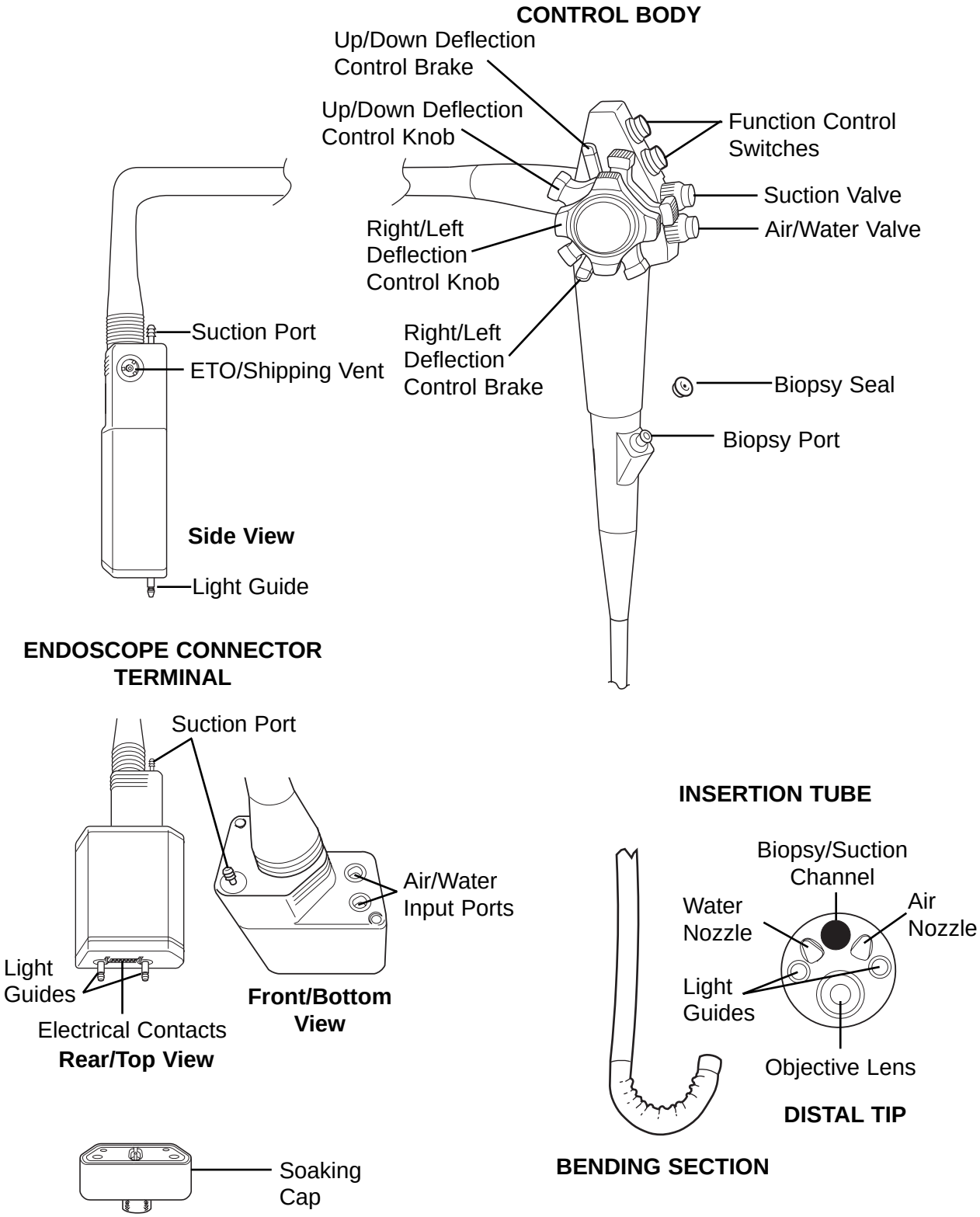
	**04060**	Lamp Replacement Assembly
	**33915**	Electrosurgical Ground Kit

VLX-20 Light Source Includes:

	**45500**	Light Source
	**45510**	Water Bottle
	**761076-0**	Power Cord
	**45512**	S-Video Cable
	**45520**	Cleaning Bottle

Nomenclature and Function

Flexible VideoEndoscope (200 Series)



VideoEndoscope

Nomenclature and Function (continued)

Flexible VideoEndoscope

CONTROL BODY

Suction Valve – Depress to aspirate fluids or air through the biopsy/suction channel.

Air/Water Valve – Covering the vent hole in the top of the valve delivers pressurized air through the air nozzle in the distal tip. Covering the hole and fully depressing the valve delivers pressurized water through the water nozzle in the distal tip.

Biopsy Seal – Allows passage of accessories while preventing escape of fluids and air.

Biopsy Port – For introduction of biopsy forceps and other accessories.

Up/Down Deflection Control Knob – Rotation of the knob toward the operator will deflect the bending section up. Rotation away will deflect the bending section down.

Right/Left Deflection Control Knob – Rotation of the knob toward the operator will deflect bending section left. Rotation away will deflect the bending section right.

Up/Down Deflection Lock – When this lever is in the "F" (Free) position (rotated fully clockwise) the bending section moves freely. When the brake lever is rotated counterclockwise, deflection of the bending section becomes progressively more stabilized. When the lever is rotated fully counterclockwise, the bending section is locked into position. Note that when the lock is engaged, deflection can still be accomplished by rotating the deflection lever.

Right/Left Deflection Lock – Function similarly to Up/Down lock.

ELECTRONIC FUNCTION CONTROLS (when connected to video printer with built-in memory).

F (Freeze) Button – Push to freeze an image.

C (Copy) Button – Push to activate the remote video printer.

V (Video) Button – Push to switch between "frozen" image (stored in printer memory) and "live" image.

INSERTION TUBE – Contains random light guides, biopsy/suction channel, air and water lines, steering cables and wires from CCD (Charge Coupled Device).

BENDING SECTION – Contains articulating vertebra that allows deflection in two planes.

DISTAL TIP

Air Nozzle – Directs pressurized air across objective lens to remove moisture and to distend cavity being examined.

Light Guides – Provide illumination of examination area.

Biopsy/Suction Channel – Opening from which biopsy forceps and other accessories exit and where fluid/debris is aspirated when the suction valve is depressed.

Objective Lens – Contains the lens system that provides depth of field and field of view.

Water Nozzle – Directs pressurized water, via the water nozzle, across objective lens to remove debris.

ENDOSCOPE CONNECTOR TERMINAL

Air/Water Input Ports – Couples with the air/water bottle to allow the introduction of pressurized air and water to the instrument.

Suction Port – Port where the auxiliary suction machine hose is attached to the instrument.

Soaking Cap – Covers electrical contacts during immersion (cleaning/disinfection).

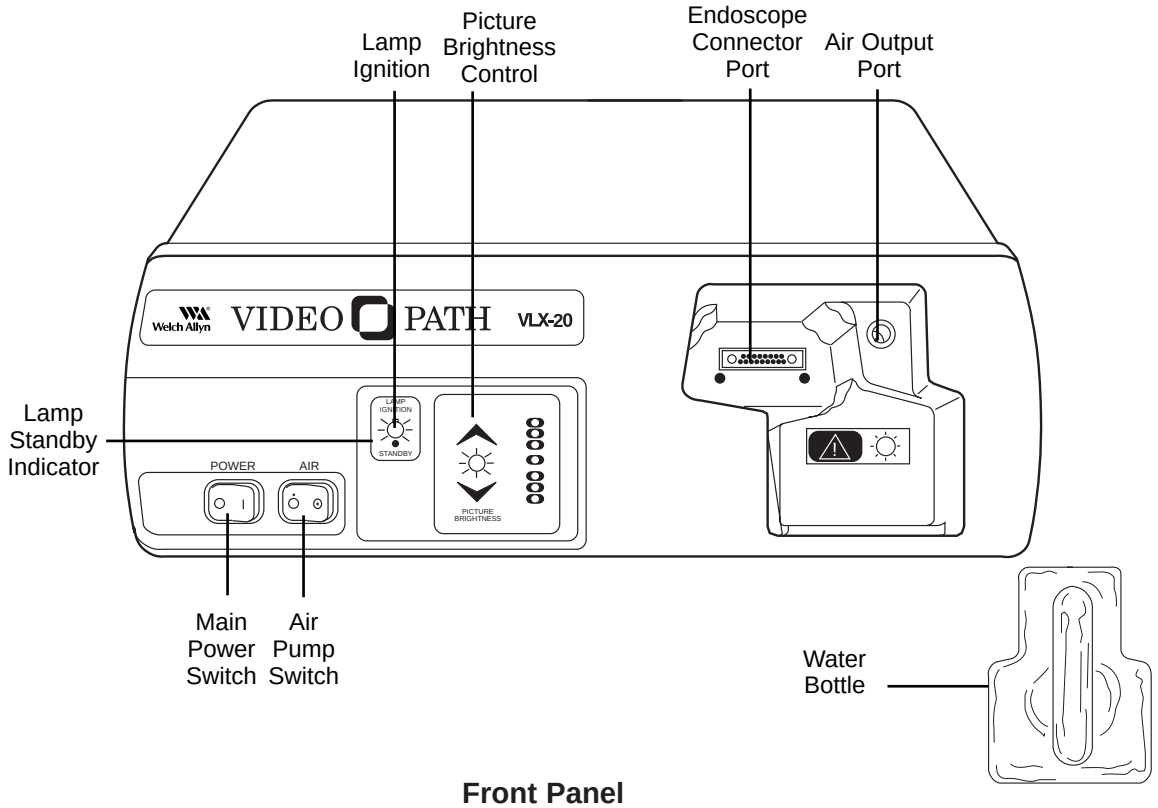
Electrical Contacts – Provides power to the endoscope and provides pathway for video signal input into the light source.

ETO/Shipping Vent – Vent where ETO/Shipping Vent Cap couples to equalize instrument's internal pressure with room pressure during shipping and ETO gas sterilization.

Light Guides – Couple to lamps in light source to provide illumination.

Nomenclature and Function (continued)

Light Source



Front Panel

Main Power Switch – Primary power control for the light source. If not activated, other controls will not function.

Air Pump Switch – Activates flow of air at air output connector in light source's endoscope connector port.

Lamp Ignition – Activates the lamps when switch is depressed and main power switch is on.

Lamp Standby Indicator – When LED blinks, lamps cannot be ignited even if lamp ignition switch is depressed.

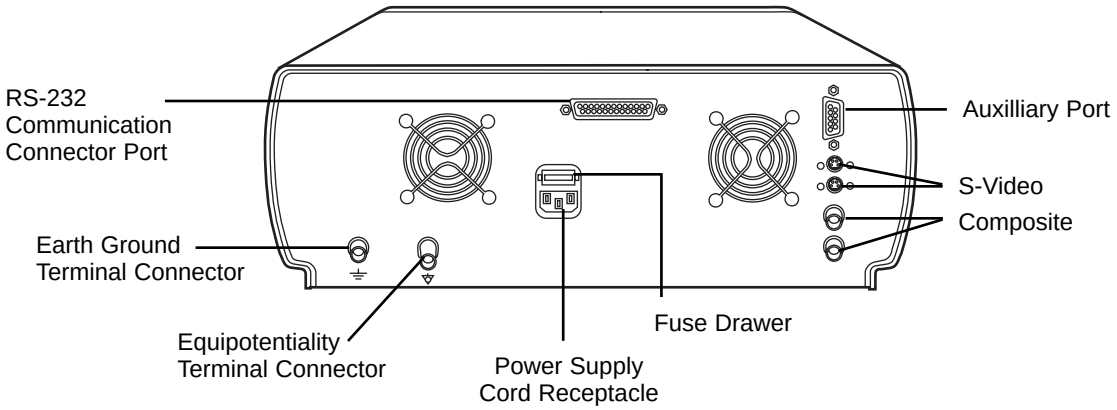
Endoscope Connector Port – Accepts VideoEndoscope connector terminal to transmit light, electrical signals, water, and air through the endoscope.

Water Bottle – Couples to endoscope connector terminal's air and water input ports and light source's air output port.

Air Output Port – Couples to water bottle to provide air and water to the endoscope.

Picture Brightness Control – Pressing up or down arrows adjusts image on monitor to desired average brightness level (level indicated by illuminated green LED).

Nomenclature and Function (continued)



Back View

Power Supply Cord Receptacle – Couples with power cord which should be plugged into an 115V hospital grade outlet.

S-Video – Outputs S-Video or Y/C, 4 pin DIN.

Composite – Outputs NTSC (composite video), BNC connector.

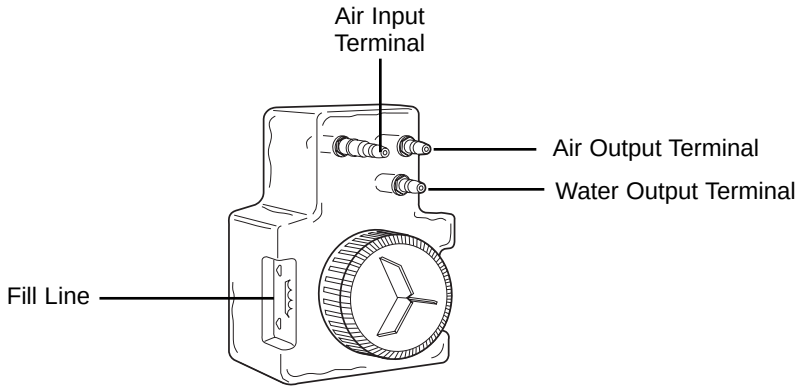
Earth Ground Terminal Connector – Provides a terminal which is connected to earth ground through the VLX-20 line cord (1/4-36 UNS-2A thread).

Equipotentiality Terminal Connector – Accepts ground connector from electrosurgery equipment to provide a secondary or redundant ground path.

RS-232 Communication Connector Port – Communication port for use with video printers.

Aux(illiary) Port – No function. Future capability.

Water Bottle/Cleaning Bottle



Water Bottle

Air Input Terminal – Couples to light source air output port.

Air Output Terminal – Couples to VideoEndoscope air input port.

Water Output Terminal – Couples to VideoEndoscope water input port.

Fill Line – Indicates maximum water level bottle should be filled to.

NOTE: The Cleaning bottle is identical to water bottle with the exception that it allows fluid to be introduced into the air input port of the endoscope. The Cleaning bottle can be easily identified via the **red caution** label on the front of the bottle.

Preparation and Inspection for Use

Prior to Initial Use

Before preparation or set up of the equipment, check all components received against the list of components (see components section) to verify a complete set. If parts are missing, please notify Welch Allyn. Review the nomenclature, set-up, operation, and cleaning/disinfection sections to become familiar with the equipment.

Specifically, inspect:

Video Endoscope

Insertion Tube – for tears, cuts, dents, bubbles, bumps

Control Section – depress valves and test bending section deflection to assure smooth rotation of controls.

Biopsy Port – pass cleaning brush through biopsy/suction channel to verify smooth passage

Leak Test – the watertight integrity of the instrument should be verified following the procedures outlined on page 25.

Light Source

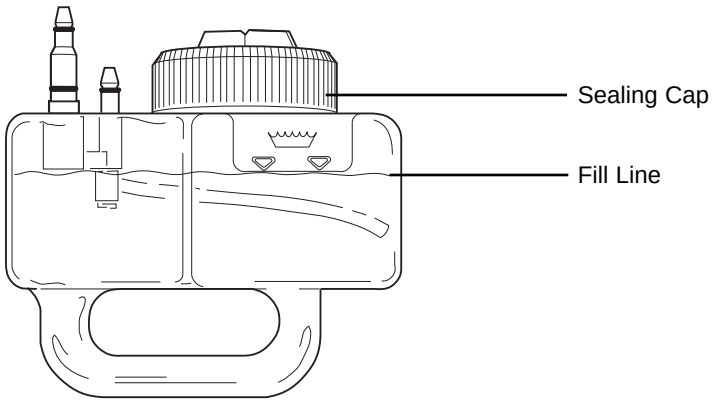
Cabinet – for any dents, scratches or other abnormalities

Water Bottle – for any cracks, leaks, etc.

System Set-up

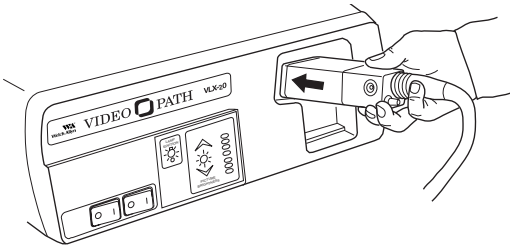
NOTE: The instrument should be cleaned and disinfected prior to initial use, following the steps starting on page 23 and 29.

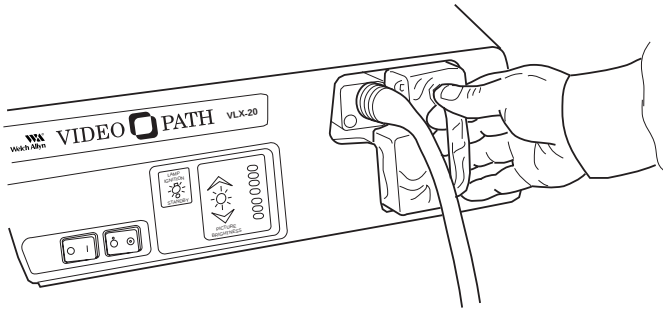
1. Connect the power cord to the power cord receptacle on the back of the light source.
2. Plug the remaining end of the power cord into a properly grounded 100-240 volt AC outlet.
3. Fill the water bottle to the fill line with clean, distilled water and replace the sealing cap.



Preparation and Inspection for Use (continued)

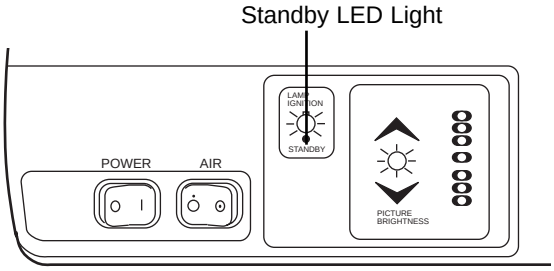
4. Plug the endoscope connector terminal into the endoscope connector port of the light source. The endoscope connector terminal should fully engage and “click” into place.



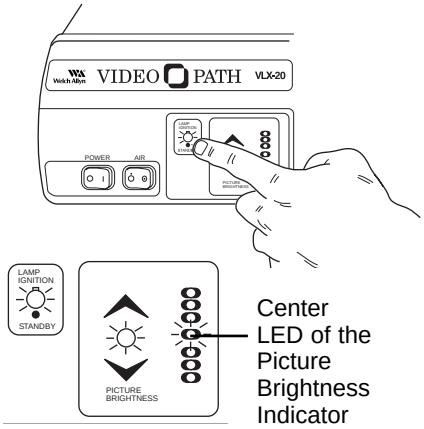


5. Plug the water bottle into the recessed area on the front panel of the light source. This will couple the water bottle both to the light source air output port and the VideoSigmoidoscope connector terminal air/water input ports.

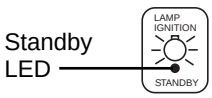
6. Activate the Power switch on the front panel. The green Lamp Ignition/Stand-By light will blink for approximately 11 seconds. Once the LED stops blinking, the lamps are ready to be ignited.



7. Once the green Lamp Ignition/Standby light remains lit, press the Lamp Ignition Switch. The lamps will ignite and the Lamp Ignition/Standby light will go out. The lamps require 11 seconds to warm up. This length of time will be indicated by the center LED of the Picture Brightness Indicator, which blinks until the lamps reach full intensity. Once the Picture Brightness Indicator remains constant, the lamps are fully warmed up, and the system is ready for use.



NOTE: If the Light Source is powered up without having the Video-Endoscope attached, the lamp ignition Standby LED will remain blinking and lamp ignition cannot occur.



WARNING: Once lamps have been lit, do not remove the instrument from the light source without turning the main power switch off or putting the lamps on Stand-By by pressing the Lamp Ignition switch. If the VideoEndoscope is removed from the light source, avoid looking directly into the intense light provided by the light source to prevent damage to your eyes.

8. Activate the Air switch to verify function of the pump. Air should begin to flow immediately out of the top hole in the air/water valve on the control section of the instrument.

WARNING: It is essential that the instruction manual for the VLX-20 Light Source be reviewed in detail prior to using the system.

Physical System Inspection

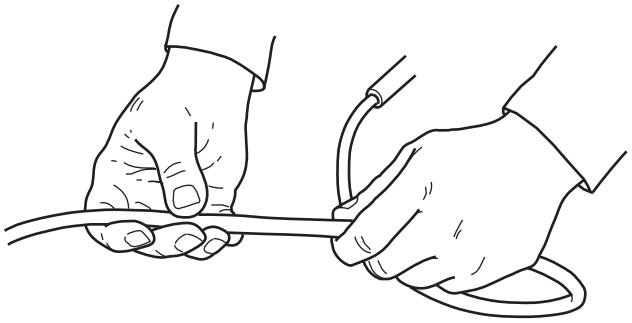
Before inspecting the system, the VideoEndoscope should be tested to verify that it is watertight. Refer to the Leak Test procedures on page 25.

The following steps should be repeated prior to every procedure to verify that the system is working properly. If any problem is encountered, immediately consult the troubleshooting section of this manual or contact Welch Allyn Customer Service (1-800-535-6663) for assistance.

Insertion Tube, Umbilical Tube, and Bending Section

NOTE: The insertion tube may have a slight curve when first removed from the package due to product settling. This can be eliminated by storing the instrument with the insertion tube in a straight position.

1. Inspect the insertion tube and bending section for tears, cuts, dents, bubbles, bumps or other abnormalities on the surface.
2. Run your fingers carefully over the entire length of the insertion tube and bending section to check for protruding braid.



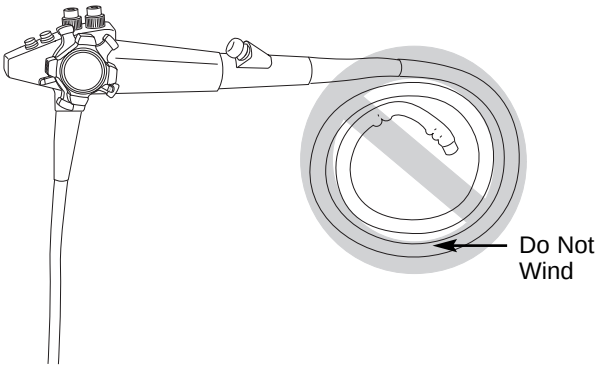
3. Inspect the umbilical cord for outward indications of damage (e.g., dents, cuts).

CAUTION: To avoid harm to the patient and further damage to the equipment, Do Not use a VideoEndoscope with outward signs of damage.

NOTE: Make sure the distal end of the instrument is not damaged. The distal end has an atraumatic non-removable tip. Do Not try to remove the distal tip. Doing so will result in damage to the distal portion of the instrument.

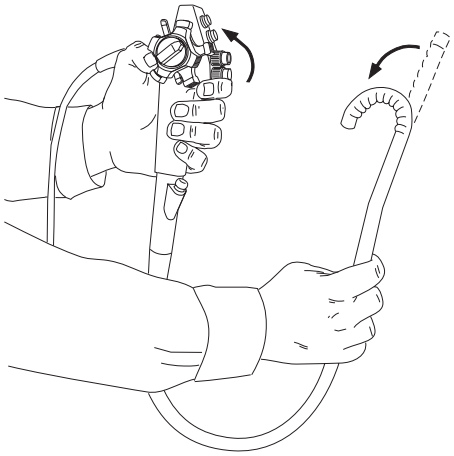
Preparation and Inspection for Use (continued)

CAUTION: Do Not wind the insertion tube into a tight radius. Serious internal damage could result. Proper storage procedures are outlined on page 39.



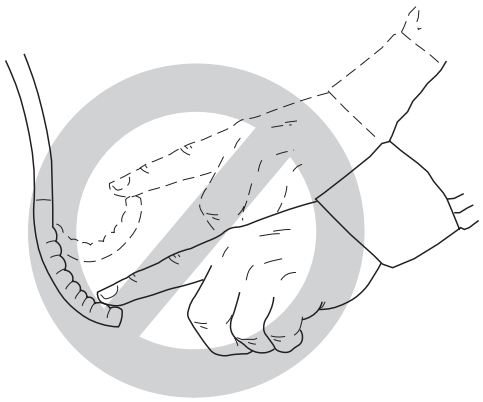
Deflection Controls

1. Rotate the up/down and right/left deflection control knobs to the limit in each direction. The knobs should rotate without excess friction or grinding.



NOTE: Do Not attempt to rotate the deflection knobs past their limits. This can result in severe damage to the steering mechanism.

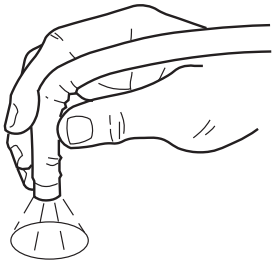
2. Make sure the bending section can be locked into position by engaging the deflection brakes. The brakes are disengaged when the brake levers are rotated fully clockwise (looking at the steering knobs straight on). The bending section will move freely. As the brake levers are rotated counterclockwise, the bending section becomes progressively stiffer. When the brake levers are rotated fully counterclockwise, the bending section is locked into position.



CAUTION: Do Not deflect the bending section of the VideoEndoscope by hand. This applies excess force to the deflection mechanism and may result in steering cable failure. If the deflection controls do not operate smoothly do not use the VideoEndoscope. Doing so may result in injury to the patient or further damage to the instrument.

Inspection of Light Guides and Optics

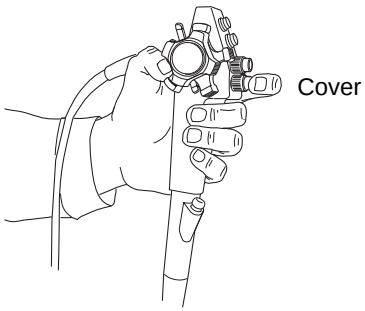
1. With the lamps on, hold the distal tip approximately 40mm from any surface.
2. Verify light is being emitted from both light guides.

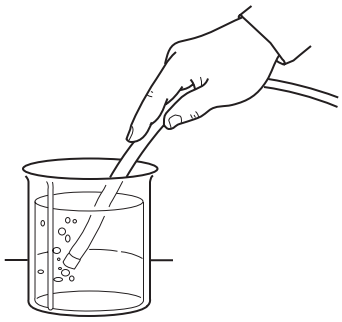


Preparation and Inspection for Use (continued)

Inspection of Air Feed Valve

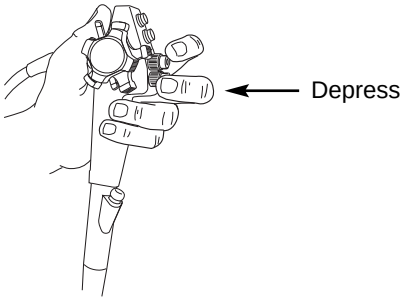
1. Place the tip of the bending section into a container of clear water. Cover the hole in the top of the air/water feed valve (green ring). Do not depress the valve. Air should flow freely from the air nozzle in the distal tip of the instrument and the water should bubble vigorously.
2. Remove your finger from the valve – the bubbling should end immediately.

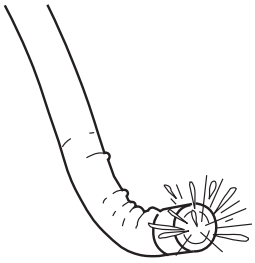




Inspection of Water Feed Valve

1. Depress the air/water valve completely to initiate the flow of water from the water nozzle in the distal tip of the instrument. Water should flow in a constant stream over the objective lens and light guides. Upon initial set-up, depress and hold the valve for several seconds for water to fill the entire line.

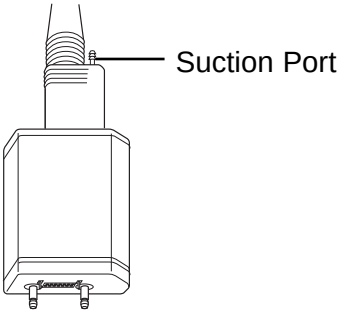


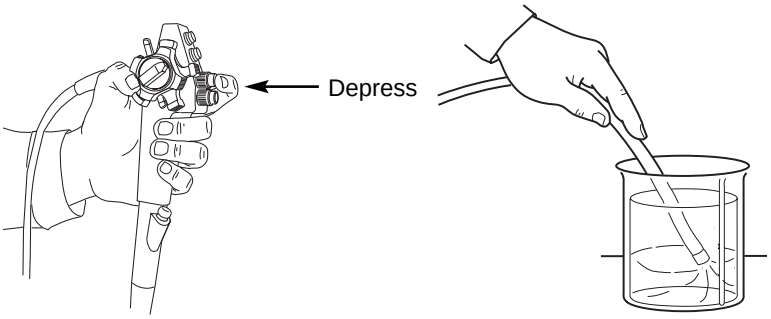


NOTE: If air or water do not flow from the distal tip, refer to the Troubleshooting section (page 43).

Inspection of Suction Mechanism

1. Connect the suction tubing from the suction machine to the Suction Port hose barb on the endoscope connector terminal.
2. Immerse the distal tip of the bending section into clear water and completely depress the suction valve (orange ring). Make sure biopsy seal is in place.
3. Verify aspiration by viewing water flow into suction receptacle. Releasing valve should stop suction immediately.

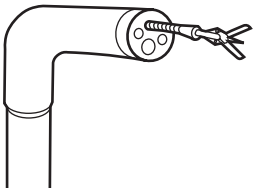




NOTE: It is important that the rubber biopsy seal on the biopsy port is in good condition. Worn seals will result in poor suction and leakage and should be replaced.

Inspection of Biopsy/Suction Channel

1. Check for kinks in the flexible shaft of the biopsy forceps.
2. Clean any debris from the biopsy forceps before using them.
3. Make sure the handle mechanism on the forceps works freely and the jaws open and close freely.
4. Close and inspect the jaws of the forceps to make sure the cups are in proper alignment. If there is a spike in the forceps, make sure the spike is completely straight and within the cups.



WARNING: It is important that forceps or accessories not be used if they show any sign of damage or if they do not operate correctly. If the forceps or an accessory does not work properly during a procedure, serious injury to the patient could result. Use of damaged forceps or accessories could also result in damage to the VideoEndoscope.

5. Straighten the VideoEndoscope and insert the forceps through the biopsy port. If resistance is encountered, contact Welch Allyn Technical Service. Do Not insert the accessory further. Damage could occur to the instrument. Do Not use the VideoEndoscope.

Operations

Procedure

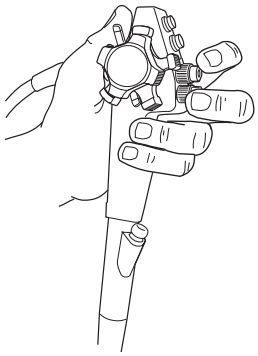
The methods and techniques of flexible colonoscopy are well-defined and documented. Endoscopy training seminars and preceptorship programs are also in existence worldwide.

No attempt is made in this manual to outline the medical procedure or techniques of flexible colonoscopy. The physician should always take care to understand the clinical background of each patient and the possible contraindications of the procedure.

Before beginning the procedure, make sure the patient is prepared for the examination using the normal steps required for endoscopy.

Holding the Instrument

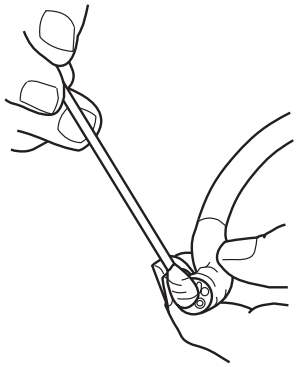
The control section is designed for the left hand. The "V" formed by the left thumb and index finger should be positioned beneath the area where the umbilical cord exits the control section. The suction and air/water valves are controlled by the index finger and middle finger respectively. The up/down deflection control is operated by the thumb. The right hand is used to advance and rotate (torque) the insertion tube. In some instances, it may be necessary to have an assistant hold the insertion tube while the right/left deflection control is rotated by the right hand.



Preparation Before Insertion of the VideoEndoscope

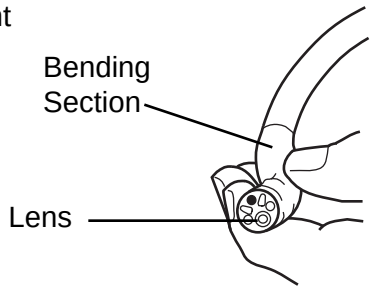
WARNING: Make sure the VideoEndoscope is properly disinfected or sterilized prior to every use. Current infection control guidelines require that VideoEndoscopes and their patient contact accessories be subjected to high level disinfection or sterilization.

1. Use a clean gauze to gently wipe the insertion tube.



2. Moisten a cotton-tip swab with alcohol and gently clean the objective lens on the distal tip. If a lens cleaner (anti-fogging agent) is used, apply it first to gauze or other applicator. Make sure to wipe off all excess cleaner.

3. Apply a medical grade water soluble lubricant (e.g., KY Jelly) to the bending section and insertion tube. Do Not use petroleum based lubricants. Do Not contaminate the lens with lubricant.



Insertion and Withdrawal

1. Slowly insert the lubricated instrument.
2. Use the deflection controls to guide the instrument through the lumen. The deflection of the tip should be done under direct vision in a gentle and deliberate manner.

WARNING: If resistance is encountered, Do Not force the deflection controls. Doing so may result in serious injury to the patient and/or damage the instrument.

Do Not advance the instrument if the lumen is not visible. Blind advancement could result in perforation of the patient's colon.

If during the procedure, the deflection controls cease to function or the image is lost due to a power shortage, lamp or processor failure, etc., terminate the examination. Return one (or both) of the deflection controls to the neutral position. Slowly withdraw the VideoEndoscope from the patient. Do Not operate the controls during withdrawal.

3. A collapsed lumen can be opened by insufflation. Cover the hole on the top of the air/water valve to inflate the colon. Adequate insufflation can be maintained by insufflation and periodic aspiration of air. Use the suction control to decrease the level of insufflation.

WARNING: It must be recognized that variations in air flow (pressure and volume) for patient insufflation may exist from one manufacturer's equipment (light source and/or endoscope) to another. It is, therefore, important to closely monitor the patient at all times and to aspirate excessive air to prevent over insufflation and patient discomfort.

4. Fluid, secretions, and liquid stool can be aspirated by depressing the suction valve, thus improving visualization. Do Not try to aspirate solid material since this will clog the suction channel.

NOTE: When using Welch Allyn endoscopes for the aspiration of waste substances such as fecal materials, always follow local waste disposal practices and procedures to minimize hazards due to contamination.

CAUTION: Care should be taken to avoid sucking mucosa into the suction channel. This phenomena can result in a "suction polyp" that can be mistaken for a lesion.

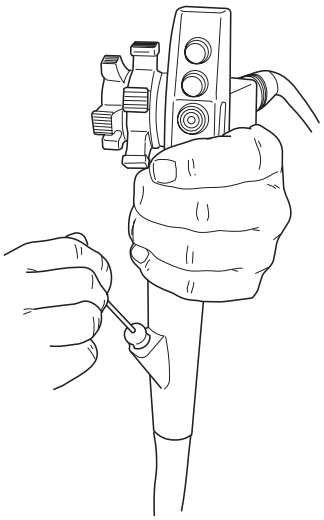
5. Lubricant, mucous and fecal materials can cloud or fog the objective lens. Use the air/water and suction control valves alternately to clean the objective lens.

NOTE: Water drops retained on the lens can be removed by covering the hole on top of the air/water valve, pushing air through the scope and over the lens.

6. Before removing the VideoEndoscope, aspirate any remaining air to reduce any patient discomfort.
7. Before withdrawing the scope, return the bending section to the neutral position. Always withdraw the VideoEndoscope under direct visualization.

Biopsy Passage

1. Biopsy forceps and accessories should be inserted through the biopsy seal and into the channel. Hold the forceps handle so that the jaws are **fully closed** during insertion.



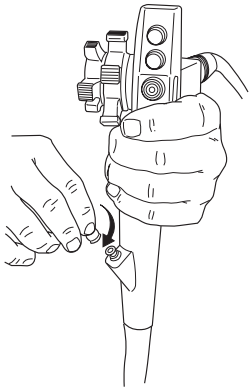
NOTE: Failure to insert the forceps in the fully closed position may cause serious damage to the biopsy/suction line.

Temporary resistance will be experienced when the cups are first passed through the seal. Advance the forceps using short strokes, started by grasping the forceps sheath tightly at about 5cm from the cups.

WARNING: If resistance is encountered during the passage through the bending section, relax the deflection angle until the passage is smooth and easy. Wetting the forceps with water or a medical grade silicone lubricant will promote easier passage. Never apply excessive pressure when inserting any accessory into the biopsy channel, since the channel may be damaged, resulting in malfunction of the VideoEndoscope and costly repairs.

If the biopsy seal “Splits” or leaks while the VideoEndoscope is in place, remove the defective seal and replace it.

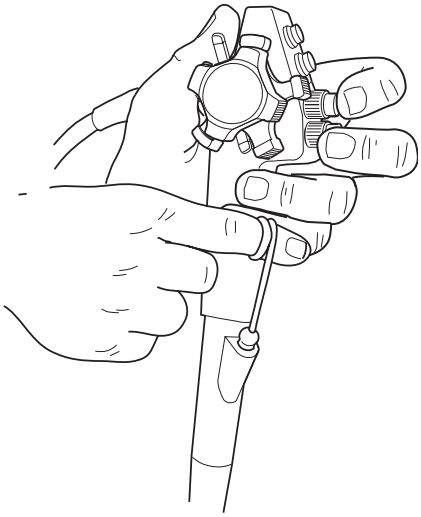
NOTE: When replacing the biopsy seal, rotate the seal one full turn clockwise after pushing on the luer lock fitting to insure a proper seal.



NOTE: Always flush the biopsy/suction channel immediately after a procedure by aspirating clear water through the channel (see the Cleaning instructions). This flushing will assist passage of instruments in subsequent procedures.

2. Collect a tissue sample by opening the forceps and advancing the open cups up against the mucosa. Carefully close the cups until resistance is felt, and then hold. Gently pull back on the forceps until a small tissue sample is removed. Always keep the accessory in view during advancement.
3. Withdraw the forceps with the cups closed. Opening the cups during withdrawal may damage the biopsy channel.

NOTE: If the forceps fail to close during a procedure, close the cups by winding the proximal portion of the forceps cable around your index finger. If the forceps still do not close, retract the cups as close as possible to the distal tip and slowly withdraw the instrument under direct visualization.



Because of the effect that accessories used in the biopsy/suction channel of the VideoEndoscope can have on the performance of the VideoEndoscope itself, it is strongly recommended that only Welch Allyn accessories be used with Welch Allyn instruments. If a unique or highly specialized accessory is available from another source, please contact Welch Allyn to arrange for a test of its compatibility before using it through the Welch Allyn VideoEndoscope.

Electrosurgery

The user must carefully read and understand all the instructions in the operating manuals supplied with the electrosurgical generator and associated accessories. All electrosurgical equipment must be thoroughly inspected prior to use. Only the user can determine if the condition of the electrosurgical generator and accessories is correct and safe for clinical use.

1. The electrosurgical accessories should be introduced through the VideoSigmoidoscope in the same manner as described for the biopsy forceps in the preceding section.
2. The active portion of the electrosurgical accessory should always be clearly visualized before applying electrical energy to the instrument.

CAUTION: High frequency surgical equipment used with the endoscope must comply with the IEC 60601-2-2, Particular Requirements for the Safety of High Frequency Surgical Equipment.

CAUTION: The chassis of the high frequency surgical equipment, if accessible, should be connected to the Equipotentiality Terminal of the VLX-20 Light Source to eliminate the potential of RF voltage potential between the two devices during electrosurgery.

CAUTION: Before use, inspect the insulation of all endoscopic accessories designed for high frequency electrosurgery.

NOTE: The maximum rated recurring peak voltage of the high frequency generator used with this endoscope for electrosurgery shall not exceed these limits.

Cut Mode	1000 Volts peak
Coagulation Burst Mode	2000 Volts peak
Coagulation Spray Mode	3000 Volts peak

CAUTION: Avoid using high frequency surgical equipment where explosive gas concentrations may be in the area of use.

NOTE: The VC-200 Endoscope is Type BF and does not require electrical connection between the endoscope and the neutral electrode of the high frequency generator during electrosurgery.

Video Printer

The VC-200 VideoEndoscope, when used with the VLX-20 Light Source and compatible video printer, has the ability to capture, store and print endoscopic images. The function controls on the endoscope interface with the system for convenient control of the Freeze, Copy and Video features. The RS-232 Cable must be connected from the VLX-20 Light Source to the video printer for this feature to perform properly. Please refer to the Connection Diagrams in the VLX-20 Light Source Instruction Manual for further information. It is important that the user review and understand the instruction manuals associated with all the components of the system, including the Light Source and video printer.

To save and print an image, perform the following:

F (Freeze) Button – Push and release the button to freeze an image.

C (Copy) Button – Push and release the button to activate the print function.

V (Video) Button – Push and release the button to return to the live image after completion of the print process. Returning to the live image prior to printing a frozen image will result in the loss of the frozen image. Please refer to the instruction manual of the video printer for more detailed instructions.

Cleaning and Disinfection

Endoscope Internal Schematics

These schematic illustrations are intended to provide the user with a better understanding of how the Welch Allyn VideoEndoscope works. All the internal channels are indicated to better show their relationship to one another. This understanding should assist the user in caring for and reprocessing the VideoEndoscope.

The design of VideoEndoscopes and its components allows for efficient and effective cleaning and disinfecting by either manual methods or automated processes prior to patient use.

Standard size luer lock and/or luer-slip fittings are used on the connectors on all cleaning/disinfecting adapters and scope inlet ports. These locks and fittings easily accommodate reprocessing devices or systems available from other manufacturers.

As illustrated in the schematics, the cleaning system promotes efficient unidirectional flow of solution beginning from connections at the endoscope connector terminal, traveling up channels in the umbilical cord to the valve cylinders in the control section, passing through the channels in the insertion tube and finally exiting nozzles or channel openings at the distal tip of the scope.

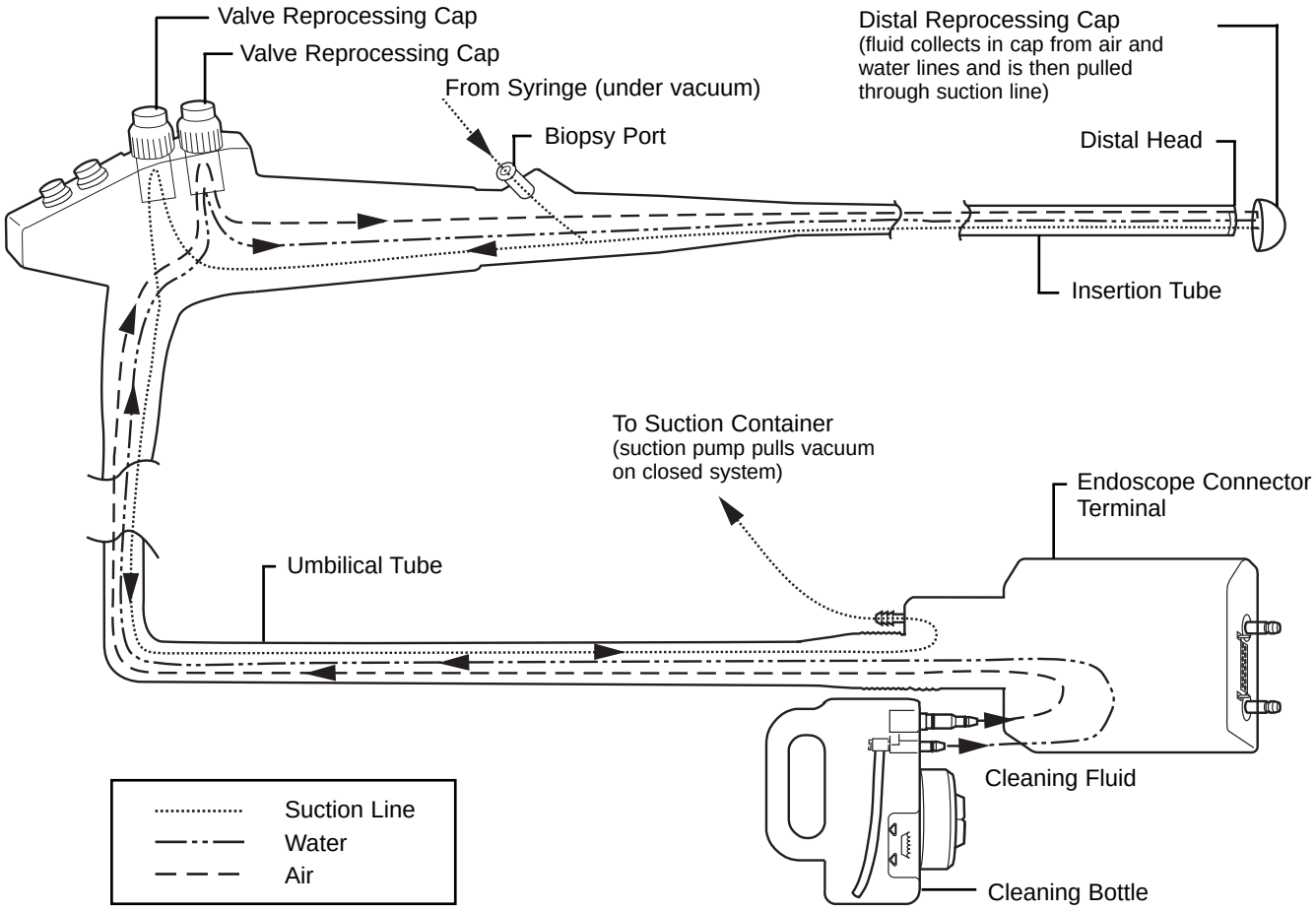
The elimination of multiple branching channels, combined with a direct and straightforward pathway for solutions to travel maximizes flow efficiency and ensures contact of disinfectant/sterilant with all internally exposed channel surfaces.

Cleaning and Disinfection (continued)

WARNING: It is imperative that flexible VideoEndoscopes and other semi-critical devices be reprocessed such that high level disinfection is achieved with an EPA registered sterilant/disinfectant. It should be noted that any endoscope automated reprocessing device or system* must be cleared for marketing by the FDA via the 510 (k) premarket notification or PMA approval process.

Only reprocessing solutions/systems satisfying the above conditions and tested and found to be compatible by Welch Allyn should be used with Welch Allyn products.

*Liquid chemical germicides (disinfectants/sterilants) to reprocess medical devices come under FDA regulation and new products must, therefore, undergo a 510 (k) premarket notification submission prior to introduction into interstate commerce.

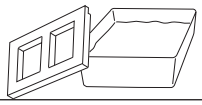
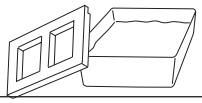
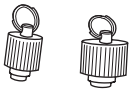
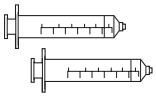
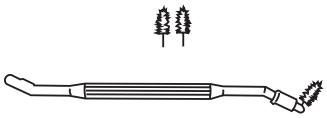
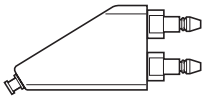
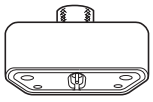
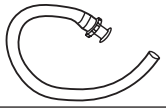


Internal Schematic

NOTE: Endoscopic instruments should be meticulously cleaned immediately after each use prior to disinfection or sterilization. Endoscopes are delicate and will degrade, if not cleaned properly, due to the effects of digestive contents (e.g., blood, mucous). The methods outlined on the following pages have been tested and verified to have no damaging effects. Therefore, it is important to adhere to these procedures.3. After the recommended soaking time, remove the accessory from the solution.

Cleaning and Disinfection (continued)

Required Equipment (for cleaning and disinfection):

	Basin of Clean Water
	Basin of Enzymatic Solution
	Gauze Pads
	Disposable Gloves
	31020 Channel Cleaning Brush
	**31021** Valve Reprocessing Caps
	**31023** 60cc Syringes (2 each)
	**33924** Air/Water Nozzle Cleaning Brush
	**31027** Reprocessing Adapter
	31030 Distal Reprocessing Cap (semi-automated cleaning only)
	**31028** Soaking Cap
	31037 Leak Tester
	33918 Valve Lubricant
	**31038** Suction Reprocessing Adapter
	31031 Valve Well Cleaning Brush

WARNING: The importance of meticulous mechanical cleaning of Video Endoscopes cannot be overemphasized. Prior to disinfection or sterilization, all instruments must be scrupulously cleaned. Failure to do so could result in incomplete or ineffective disinfection and/or sterilization.

The bending section of the instrument should be handled with care during the cleaning process. The most common failure that results in an instrument being returned for repair is a leak in the bending section rubber due to a pin hole leak. Do Not strike the bending section against any hard surface or use abrasive material to wipe clean.

Semi-Automated Cleaning Method

(Utilizing the #45520 Cleaning Bottle)

The following steps should be performed immediately after removal of the instrument from a patient. For further clarification of the channels affected by this process, please refer to the internal schematic on page 21.

NOTE: Protective garments (i.e., gloves, gowns, face masks or shields) should always be worn during the cleaning process to minimize the risk of cross contamination.

Cleaning at the Examination Room

Power-off and Wipedown

Remove scope from patient. Turn off suction pump and light source. Leave the scope plugged into light source and suction tubing attached.

Wipe off insertion tube with enzymatic cleaner and gauze to remove any debris.

Perform Semi-Automated Cleaning Process using enzymatic cleaner.

Note: If for some reason the Semi-Automated Cleaning Process cannot be performed, refer to the Manual Cleaning Process outlined later in this section.

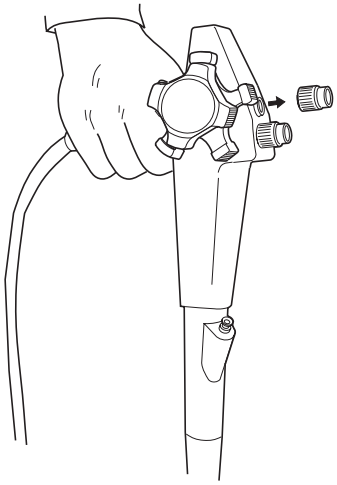
Semi-Automated Cleaning Process

Enzymatic Cleaner

See list of approved enzymatic cleaners on page 35.

Remove Water Bottle (45510) from light source. Locate the Cleaning Bottle (45520) and fill it to the line with enzymatic cleaner. Dry excess fluid from the exterior of the bottle and insert it into the light source.

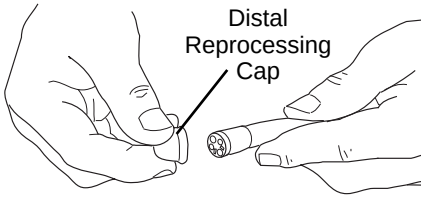
Remove valve plungers and biopsy seal from the scope and place them in a small container of enzymatic cleaner.

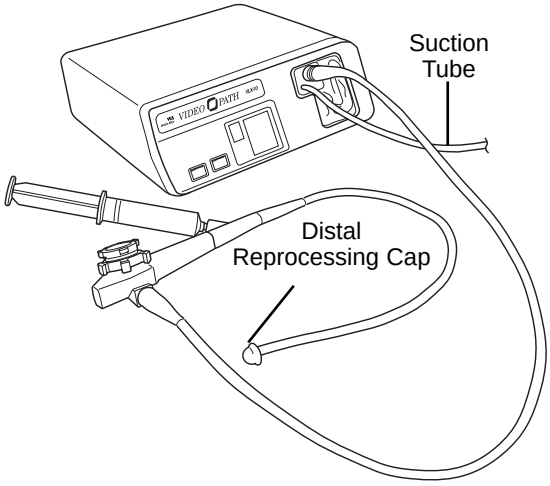


Cleaning and Disinfection (continued)

Replace the plungers with the corresponding color-coded Valve Reprocessing Caps (31021). Attach Distal Reprocessing Cap (31030).

Load a 60cc (31023) syringe with enzymatic cleaner. Attach to the biopsy port.



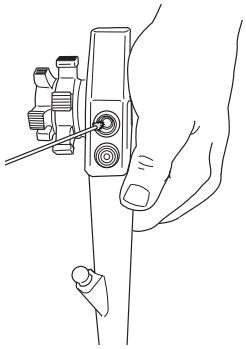


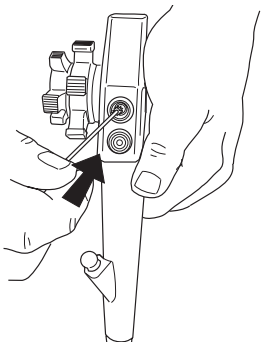
Turn on suction pump. Power up the light source and turn on the air pump. Run until no enzymatic cleaner remains in the cleaning bottle. Empty the suction pump collection bottle periodically throughout the procedure. When completed, turn off the light source and then the suction pump.

Disconnect the suction pump tubing from the suction port. Remove the syringe, valve reprocessing caps and the distal reprocessing cap.

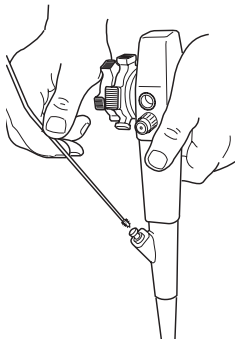
Mechanically Cleaning the Channels

The Channel Cleaning Brush (31020) can now be used to clean the various channels. Insert the brush into the suction valve well, directing it towards the opening in the side of the wall which is furthest away from the deflection knobs. Advance the brush until it exits the suction port on the endoscope connection terminal. Clean away any debris with a soft, lint-free gauze pad moistened with enzymatic cleaner and repeat until debris no longer appears on the brush.



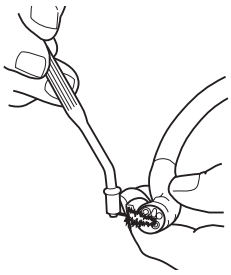


Next, insert the channel cleaning brush into the open suction valve well and direct it towards the bottom of the channel. Feed the brush through the opening until resistance is felt (approx. 15 cm). Do not use excessive force. Withdraw the brush and clean away any debris using a gauze pad moistened with enzymatic cleaner. Repeat the process until debris no longer appears on the brush.



Insert the brush into the open biopsy port and advance it until it exits from the distal tip of the instrument. Remove debris from the brush with a gauze pad and withdraw it from the channel. Repeat until no debris appears on the brush.

Insert the Suction Valve Well Cleaning Brush (31031) into the suction valve well and clean the surface of the well by rotating the brush while inserting and removing.



Using the Air/Water Nozzle Cleaning Brush (33924), clean the nozzles at the distal tip of the instrument.

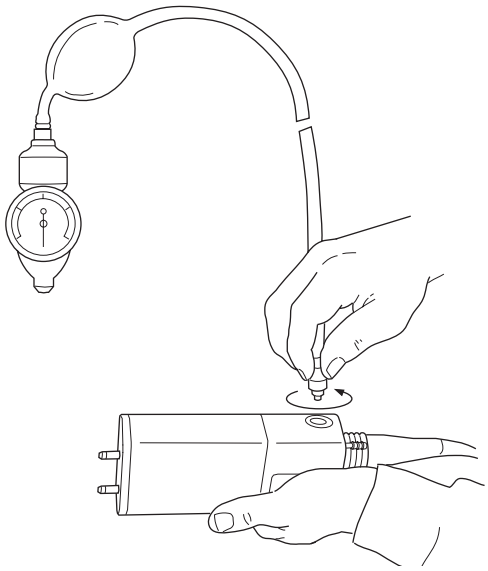
Cleaning and Disinfection (continued)

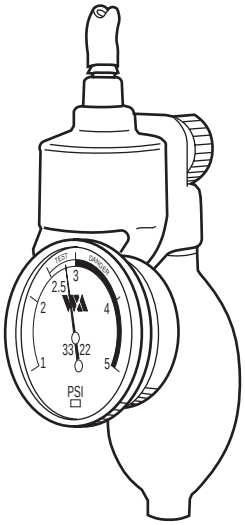
Leakage Testing

Stage 1

Remove the cleaning bottle and scope from the light source.

After making sure that the Leakage Tester (31037) and the ETO vent on the endoscope connector terminal are dry, attach the leakage tester to the ETO vent. They should be screwed together until snug to insure a watertight seal.





After making sure that the pressure release valve on the back of the gauge is closed, (turn fully counter-clockwise) pressurize the inside of the instrument by pumping the hand bulb until the indicator needle is within the TEST zone. Do not overpressurize or the scope may be damaged.

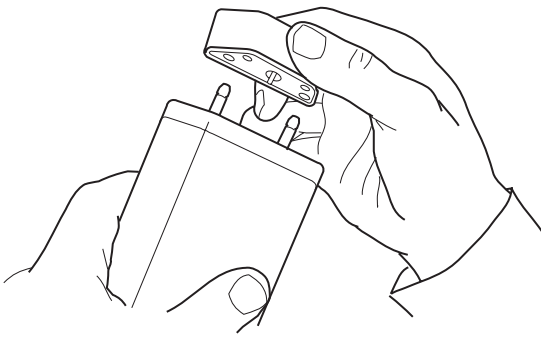
Observe the gauge indicator needle. It should remain in the TEST zone for at least one minute. If it does not remain in the TEST zone, the scope has a leak. Contact the Welch Allyn Service Dept. immediately before any further processing so that proper steps can be taken to prevent any damage to the endoscope.

Leakage Testing

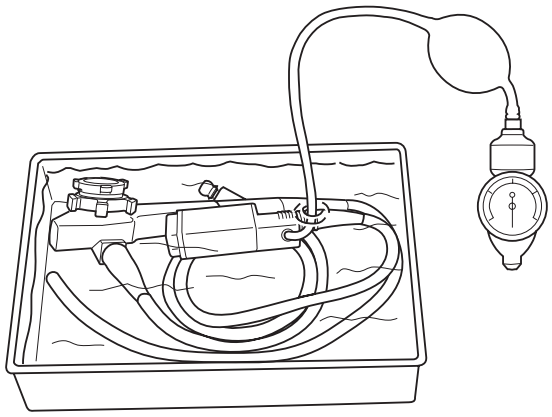
Stage 2

If no leaks are determined during the Stage 1 test, the instrument should now be tested for loss of integrity in the watertight construction due to small pinholes.

Attach the Soaking Cap (31028) to the endoscope connector terminal to seal off the electrical contacts. Make sure the leakage tester is securely attached to the ETO Vent port and that the gauge indicator needle is still in the TEST zone.



Immerse the entire instrument, with all valves and biopsy seals removed, into enzymatic cleaner. Immerse only a small part of the leakage tester tubing. Never immerse the entire leakage tester.



Carefully observe the instrument for bubbles while deflecting the distal tip in all 4 directions. Observe for at least one minute. A few bubbles may initially rise from the biopsy channel or recessed areas of the scope. This is normal. If bubbles continue to rise from the same location, a leak is indicated. Remove the scope immediately from the basin and contact the Welch Allyn Service Dept. before any further processing so that proper steps can be taken to prevent any damage to the endoscope.

Mechanically Cleaning the Exterior of the Instrument

If the scope has successfully passed the leakage test it should now be cleaned. *Make sure that the leakage tester remains securely attached to the endoscope light source connector.* While still immersed in the enzymatic cleaner, gently but thoroughly wash the entire exterior surface of the endoscope with a gauze pad moistened with enzymatic cleaner. In addition, wash the valves plungers, biopsy seal and reprocessing cap with enzymatic solution.

Clean Water Rinse

Remove the endoscope and accessories from the enzymatic solution and immerse it in a container of clean water. Rinse all components thoroughly.

After removing the instrument from the water, *open the pressure release valve on the leakage tester to release the air pressure. Remove the leakage tester*. Never connect or disconnect the leakage tester under water. The instrument will be severely damaged.

Remove the soaking cap from the light source connector.

Semi-Automated Cleaning Process

Clean Water

Refill the cleaning bottle and 60cc syringe with clean water and repeat the Semi-Automated Cleaning Process as previously described to remove enzymatic cleaner from the channels.

Remove the syringe and the distal reprocessing cap. Leave the valve reprocessing caps in place. Remove the cleaning bottle and the scope from the light source.

Now proceed with disinfection of the instrument.

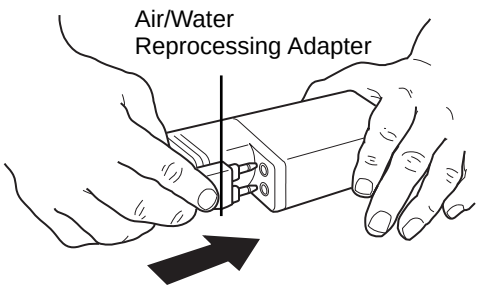
Cleaning and Disinfection (continued)

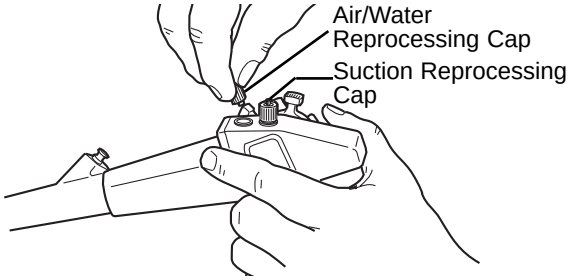
Disinfection Procedure (Total Immersion)

See the list of approved disinfectants on page 36.

Fill a covered basin with activated disinfectant to a level that will allow the entire instrument to be immersed in solution.

Connect the Air/Water Reprocessing Adapter (31027) to the air and water ports on the endoscope connector.

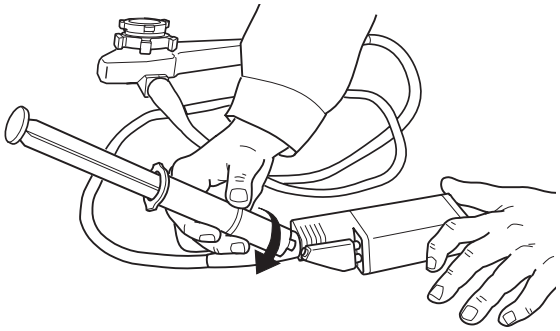




Attach the color-coded valve reprocessing caps.

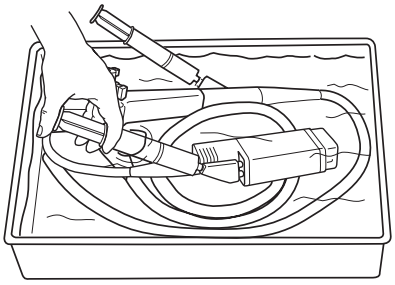
Attach the soaking cap to the endoscope connector terminal.

Place the entire endoscope into the basin making sure that all surfaces are immersed in the disinfectant. Place the air/water and suction valves and the biopsy seal into the solution as well.



Fill a 60cc syringe with disinfectant and attach it to the air/water reprocessing adapter. Fill another 60cc syringe and attach it to the biopsy port.

Depress the plungers of both syringes to fill all channels with disinfectant.



Following the solution manufacturer's recommendations, allow the instrument to soak for the proper time period.

Following the disinfection soak cycle ....

Remove the endoscope connector terminal from the disinfectant and uncouple the syringe from the adapter. Also remove the other syringe. Fill both syringes with air and reattach.

Inject air from both syringes to purge the lines of disinfectant. Repeat until bubbles appear indicating that all solution has been removed.

Remove the instrument from the solution and uncouple the syringes and the adapter.

Place the entire instrument into a basin or sink of clean water. Thoroughly wipe down the exterior of the instrument to remove any residual solution. Remove all accessories from the basin and rinse them thoroughly with clean water.

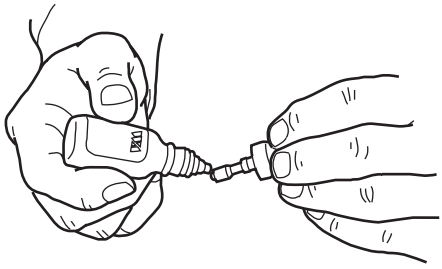
Proceed to Final Rinse.

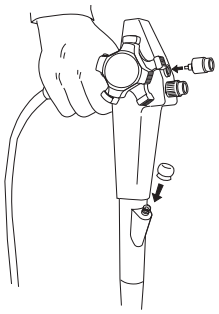
Final Rinse

Perform the *Semi-Automated Cleaning Process*, this time using *Clean Water*. Attach the light guide connector to the light source and follow the steps in the Semi-Automated Cleaning Process section above, this time using *Clean Water* instead of enzymatic solution.

The Semi-Automated Cleaning Process may be repeated with alcohol, if desired, to promote drying. Use only 70% Isopropyl alcohol.

Apply a thin coating of Welch Allyn Valve Lubricant (33918) to the Air/Water Valve “O” Rings (31024) and Suction Valve “O” Rings (31025). Remove air/water and suction caps and insert the valves into the open valve wells. Reattach the Biopsy Seal (33930) to the biopsy port.





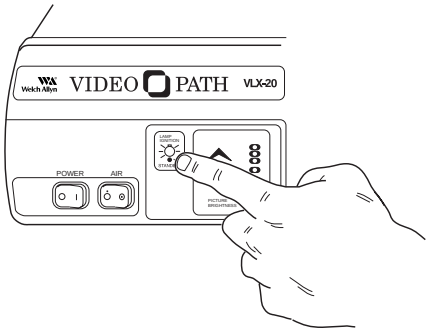
Disconnect the endoscope from the light source and hang it on the Instrument Hanger (31035) to dry.

Manual Cleaning Method

(Alternative to the Semi-Automated Cleaning Process described above)

Cleaning at the Examination Room

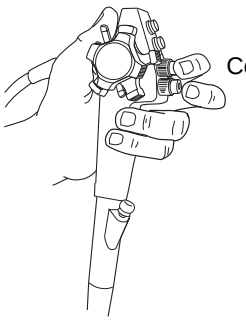
The following steps should be performed immediately after removal of the instrument from a patient.

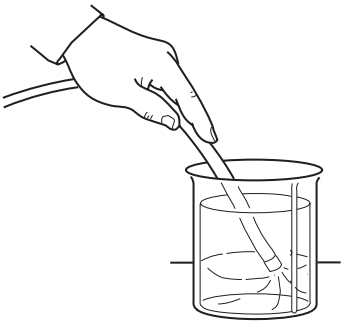


NOTE: Protective garments (i.e., gloves, gowns, face masks or shields) should always be worn during the cleaning process to minimize the risk of cross contamination.

Immediately after the instrument is removed from the patient, put the lamps on stand-by by pressing the lamp ignition switch. Next, wipe off all debris from the insertion tube with a soft, lint-free cloth moistened with enzymatic detergent. See page 35 for a list of compatible detergents.

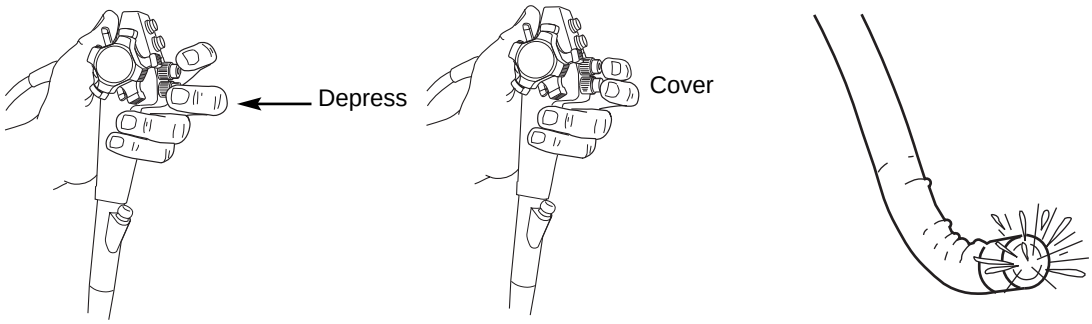
With the instrument still coupled to the suction machine, insert the distal tip into the enzymatic solution and depress the suction valve. Aspirate solution through the biopsy/suction channel until the solution exiting from the suction port is clean and free of debris. Alternate aspiration of solution and air for 5-10 seconds.





Cleaning and Disinfection (continued)

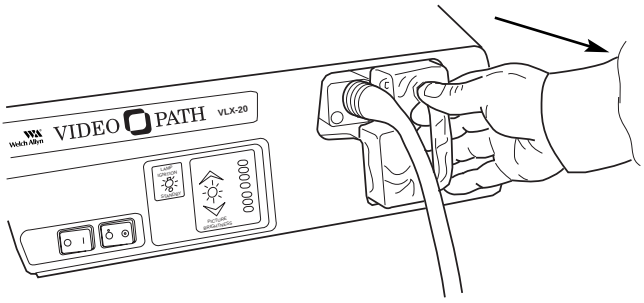
Keeping the distal tip in the container of solution (air switch is still “on”), depress the air/water feed valve (green valve) for 5-10 seconds. Release the valve and cover the hole on top for 5-10 seconds. This will expel any mucous, debris, etc. which may have entered the air and water nozzles during the procedure.



Turn off the light source and then the suction pump, and remove the suction line from the endoscope suction port.

Grasp the water bottle handle and pull back gently to disconnect the bottle from the light source.

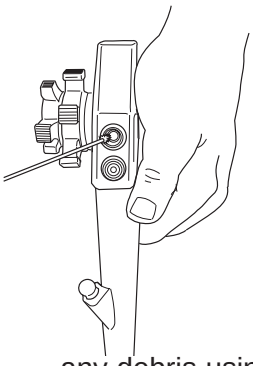
Detach the endoscope connector terminal from the light source by grasping the umbilical cord strain relief and pulling back gently. The instrument is now ready to be transported to the cleaning room for further processing.



Mechanically Cleaning the Channels

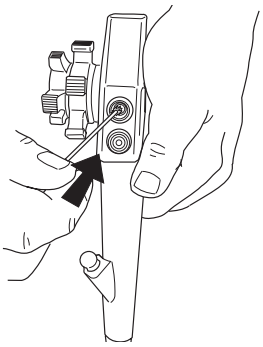
Remove the valve plungers and biopsy seal from the scope and place them in a small container of enzymatic cleaner. The Channel Cleaning Brush (31020) can now be used to clean the various channels. Insert the brush into the suction valve well, directing it towards the

Cleaning and Disinfection (continued)

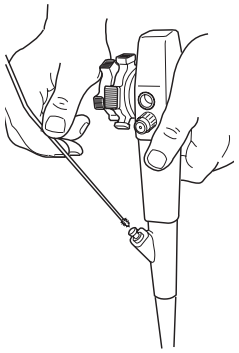


opening in the side of the wall which is furthest away from the deflection knobs. Advance the brush until it exits the suction port on the endoscope connection terminal. Clean away any debris with a soft, lint-free gauze pad moistened with enzymatic cleaner and repeat until debris no longer appears on the brush.

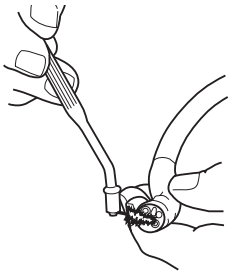
Next, insert the channel cleaning brush into the open suction valve well and direct it towards the bottom of the channel. Feed the brush through the opening until resistance is felt (approx. 15 cm). Do not use excessive force. Withdraw the brush and clean away any debris using a gauze pad moistened with enzymatic cleaner. Repeat the process until debris no longer appears on the brush.



Insert the brush into the open biopsy port and advance it until it exits from the distal tip of the instrument. Remove debris from the brush with a gauze pad and withdraw it from the channel. Repeat until no debris appears on the brush.



Insert the Suction Valve Well Cleaning Brush (31031) into the suction valve well and clean the surface of the well by rotating the brush while inserting and removing.



Using the Air/Water Nozzle Cleaning Brush (33924), clean the nozzles at the distal tip of the instrument.

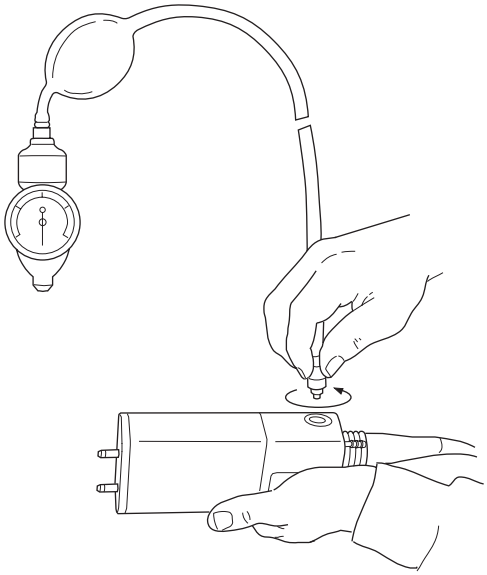
Leakage Testing

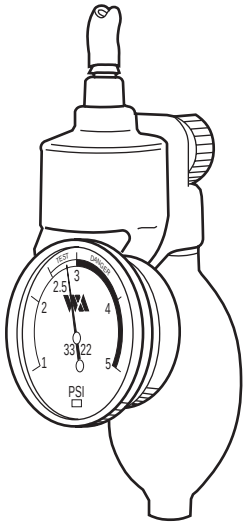
Stage 1

Remove the cleaning bottle and scope from the light source.

After making sure that the Leakage Tester (31037) and the ETO vent on the endoscope connector terminal are dry, attach the leakage tester to the ETO vent. They should be screwed together until snug to insure a watertight seal.

After making sure that the pressure release valve on the back of the gauge is closed, (turn fully counter-clockwise) pressurize the inside of the instrument by pumping the hand bulb until the indicator needle is within the TEST zone. Do not overpressurize or the scope may be damaged.





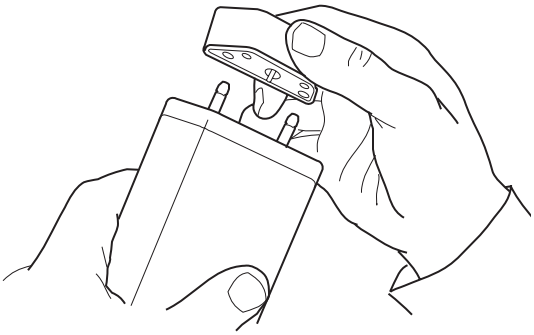
Observe the gauge indicator needle. It should remain in the TEST zone for at least one minute. If it does not remain in the TEST zone, the scope has a leak. Contact the Welch Allyn Service Dept. immediately before any further processing so that proper steps can be taken to prevent any damage to the endoscope.

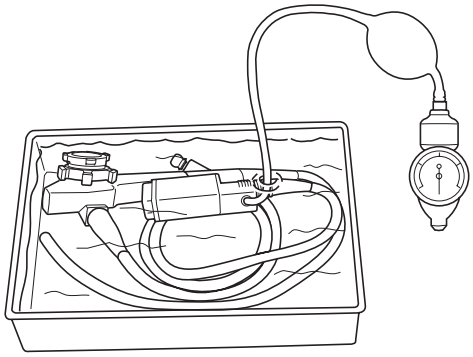
Leakage Testing

Stage 2

If no leaks are determined during the Stage 1 test, the instrument should now be tested for loss of integrity in the watertight construction due to small pinholes.

Attach the Soaking Cap (31028) to the endoscope connector terminal to seal off the electrical contacts. Make sure the leakage tester is securely attached to the ETO Vent port and that the gauge indicator needle is still in the TEST zone.





Immerse the entire instrument, with all valves and biopsy seals removed, into enzymatic cleaner. Immerse only a small part of the leakage tester tubing. Never immerse the entire leakage tester.

Cleaning and Disinfection (continued)

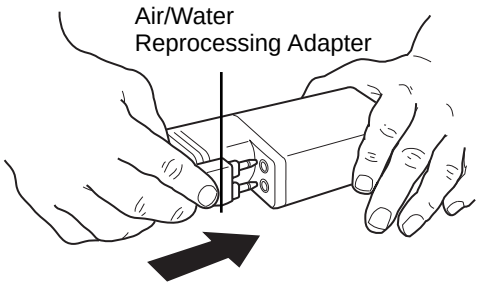
Carefully observe the instrument for bubbles while deflecting the distal tip in all 4 directions. Observe for at least one minute. A few bubbles may initially rise from the biopsy channel or recessed areas of the scope. This is normal. If bubbles continue to rise from the same location, a leak is indicated. Remove the scope immediately from the basin and contact the Welch Allyn Service Dept. before any further processing so that proper steps can be taken to prevent any damage to the endoscope.

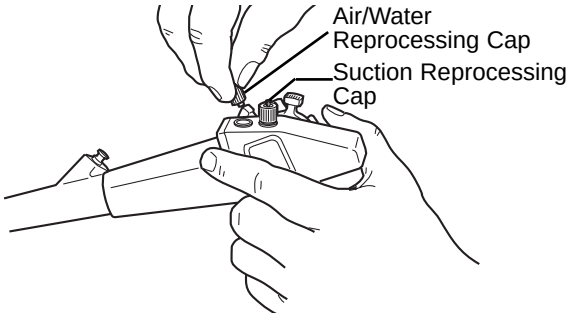
Mechanically Cleaning the Exterior of the Instrument

If the scope has successfully passed the leakage test it should now be cleaned. *Make sure that the leakage tester remains securely attached to the endoscope light source connector.* While still immersed in the enzymatic cleaner, gently but thoroughly wash the entire exterior surface of the endoscope with a gauze pad moistened with enzymatic cleaner. In addition, wash the valves plungers, biopsy seal and reprocessing cap with enzymatic solution.

Enzyme Cleaning the Channels of the Instrument

Connect the Air/Water Reprocessing Adapter (31027) to the air and water ports on the endoscope connector.

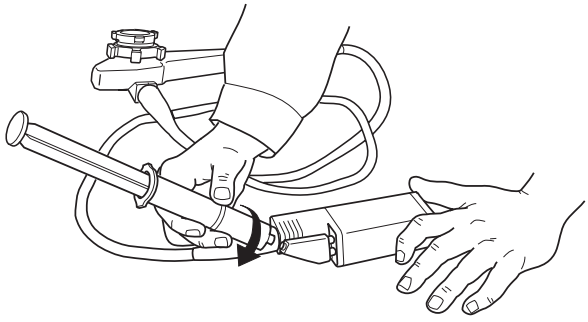




Attach the color-coded valve reprocessing caps.

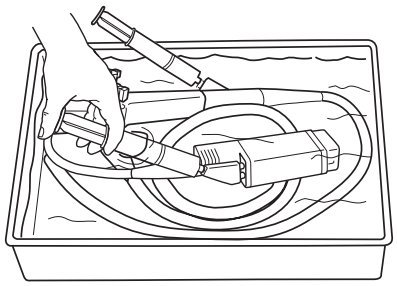
Attach the soaking cap to the endoscope connector terminal.

Fill a 60cc syringe with enzymatic cleaner and attach it to the air/water reprocessing adapter. Fill another 60cc syringe and attach it to the biopsy port.



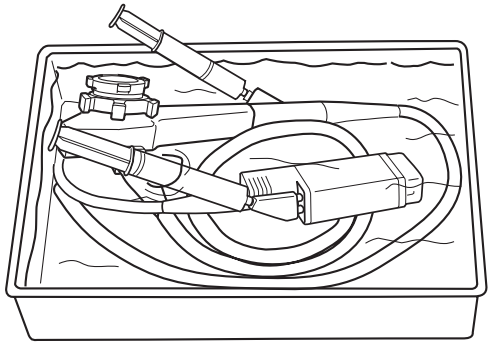
Depress the plungers of both syringes to fill all channels.

Following the solution manufacturer's recommendations, allow the instrument to soak for the proper time period.



Cleaning and Disinfection (continued)

Following the soak cycle, remove the instrument from the solution and place into a sink or basin filled with clean water, along with the air/water, suction valves and biopsy seal.



Rinse the exterior of the instrument (including valves and seal) thoroughly to remove any residual solution.

Lift the endoscope connector terminal out of the basin and remove the syringe coupled to the air/water reprossessing adapter. Refill the syringe with clean water and reattach. Inject clean water into the air and water lines to rinse. Continue until the water exiting from the air and water nozzles is clear.

Remove the syringe connected to the biopsy port and fill with clean water. Reconnect and inject water until it sprays from the open biopsy/suction channel and the suction port. Continue until the water exiting from channel and port is clear.

WARNING: Make sure that ALL internal channels (e.g., air, water, suction), the outside of the instrument, and components are thoroughly rinsed with clean water to remove any remaining enzymatic detergent solution.

Uncouple both syringes. Fill with air, recouple and inject air through the lines to dry. Repeat until water does not exit from the channels.

Lift the entire instrument out of the clean water and place on a clean, dry towel to dry (valves and biopsy seal, as well).

Gently dry the outside surfaces of the instrument with a soft, clean, lint-free cloth. Dry the objective lens with a cotton-tipped applicator. Open the pressure release valve on the leakage tester to release the air pressure. Remove the leakage tester. Never connect or disconnect the leakage tester under water. The instrument will be severely damaged.

NOTE: 70% alcohol, followed by air may be introduced through the channels to promote drying.

The instrument is now ready to be disinfected.

Enzymatic Cleaning Solutions

NOTE: Specific references to brand name is not an endorsement of efficacy as a cleaning solution. Tests have shown these solutions to be compatible with Welch Allyn endoscopes, providing the manufacturer's directions are followed.

The materials listed below are considered safe for use with the Welch Allyn VideoEndoscope if used according to the manufacturer's instructions for cleaning and in accordance with procedures detailed in the cleaning section of this manual.

Brand Name	Source	Usage
Endozime	The Ruhof Corp.	
Klenzyme	Calgon Vestal Labs	Follow
Enzy-Clean	Burnishine Products	Manufacturer's
Metrizyme	Metrex Research Corp.	Instructions
Enzol	J & J Medical	

These solutions must be enzymatic detergents or other cleaning agents specially formulated to clean endoscopes.

WARNING: Before disinfection or sterilization, be sure that any enzymatic cleaning solution is thoroughly rinsed off all surfaces. Cleaning solutions should not be combined with disinfecting or sterilizing solutions since they can alter the germicidal effectiveness.

Cleaning of Accessories – Biopsy Forceps

1. Clean reusable forceps immediately after each use since dried blood, mucous, or other debris may cause damage and make it impossible to use the forceps. If forceps are not clean prior to sterilization, the user may not be able to reprocess them properly.
2. Place the forceps in a container of warm water and enzymatic detergent. Do Not tightly coil or kink the flexible shaft.
3. Clean the handle and flexible shaft with a soft, clean cloth. Carefully and gently clean the biopsy cups, pivot pin, and needle with a soft brush.
4. Rinse any remaining detergent from the forceps by rinsing the entire forceps with clean water while manipulating the handle and biopsy cups mechanism.

NOTE: Make certain all detergent is removed from the inner mechanism of the forceps. Any remaining detergent after the water evaporated causes increased friction that may cause the mechanism not to work. Any remaining detergent also may interfere in the subsequent sterilization process.

5. After the forceps are cleaned and thoroughly rinsed, dry them gently with a soft, clean lint free cloth. Do not tightly coil or kink or put tension on the flexible shaft of the forceps.

NOTE: Clean all other reusable accessories (e.g., channel cleaning accessories, cleaning brushes) and scope components (e.g., rubber biopsy seals, air/water and suction control valves) in the same way as the forceps were cleaned.

High-Level Disinfection

The Welch Allyn VideoEndoscopes are manufactured from a variety of special materials which optimize the instrument's performance, but may not withstand some disinfection solutions and methods.

Prior to disinfection, the instrument should be thoroughly cleaned and dried following the methods previously discussed. Incomplete or improper cleaning will decrease the effectiveness of the disinfection process.

CAUTION: Before complete immersion in any disinfecting solution, make sure the instrument has been leak tested. Refer to instructions on page 31.

Disinfecting Solutions

NOTE: Specific references to brand name is not an endorsement of efficacy as a disinfecting solution. Tests have shown these solutions to be compatible with Welch Allyn endoscopes, providing the manufacturer's directions are followed.

The materials listed below are considered safe for use with the Welch Allyn flexible VideoEndoscope if used according to the manufacturer's instructions for cleaning and in accordance with procedures explained in the disinfecting section of this manual.

Solution	Brand Name	Source	Usage
Glutaraldehyde	Cidex (14 day) (2.4%)	J & J Medical	Follow Manufacturer's Instructions
	Wavicide-01 (2.5%)	Wave Energy System Inc.	
	Metricide (14 day) (2.6%)	Metrex Research Corp.	

Cleaning and Disinfection (continued)

NOTE: Do not use any other solutions until a sample has been sent to Welch Allyn for compatibility testing.

Refer to the infection control note located on the inside cover of the manual.

CAUTION: Before immersing the scope, remove the ETO/Shipping vent and place the soaking cap on the electrical contacts located on the endoscope connector terminal.

For clarity the reader may wish to refer to the internal schematic on page 21 showing the pathways involved during the disinfection process.

Sterilization and Aeration

Before sterilizing the instrument, make certain to thoroughly follow the cleaning instructions in the cleaning section of this manual. It is up to the user to determine if the sterilization procedures described in this section meet the requirements of the facility.

CAUTION: NEVER put the instrument in a steam autoclave.

Ethylene Oxide Gas Sterilization

If Ethylene Oxide (ETO) Gas sterilization is performed on this instrument, make sure to follow the steps below. This is an acceptable method of sterilization for this instrument, however the steps are different from those used for other endoscopes.

1. Properly clean and dry the instrument according to the instructions presented previously in this manual. Remove all component parts (e.g., air/water valve, suction valve, biopsy seal, etc.).

WARNING: If all surface areas are not completely dried, the ETO gas may not make contact with the contaminated surfaces, causing incomplete or ineffective sterilization.

Important: Before placing the instrument in a gas sterilizer or aeration chamber, be sure to:

- Couple the Shipping/ETO vent to the ETO vent on the endoscope connector terminal.
- The soaking cap (Part No. 31028) should not be attached and must be OFF of the electrical contacts.

WARNING: Failure to attach the Shipping/ETO Vent Cap will result in severe damage to the instrument.

NOTE: This is the opposite procedure from the immersion instructions.
- Make sure the temperature does not exceed 55°C (131°F).
- Make certain the pressure does not exceed 24 psi.
- Make sure the humidity does not exceed 70%.
- Make certain the sterilization procedure does not exceed 4 hours.

2. After ETO Gas sterilization, 72 hours of aeration at room temperature must follow. The aeration time may be shortened to 12 hours if an aeration chamber is used. The temperature must not exceed 55°C (131°F).

Cold Sterilization

If Ethylene Oxide (ETO) Gas sterilization is not available, the Welch Allyn VideoEndoscope can withstand immersion in glutaraldehyde solution for a maximum of 12 hours to achieve cold sterilization. Before fully immersing the instrument, perform the leakage test described in the Leakage Testing section.

CAUTION: NEVER IMMERSE THE ENDOSCOPE FOR MORE THAN 12 HOURS. After the 12 hours, thoroughly rinse the instrument to remove all of the glutaraldehyde solution.

After rinsing the instrument, attach the Shipping/ETO Vent to balance the internal and external humidity.

Other Sterilization Methods

In addition to the ETO and Cold Sterilization methods, Welch Allyn VideoEndoscopes are also compatible with the Steris Sterilization System/Process. Call Welch Allyn Customer Service at 1-800-535-6333 for additional information.

CAUTION: While there are other types of cleaning and/or sterilization systems or processes available, these types may have damaging effects on the instrument because of the heat sensitive nature and/or the specific biocompatible materials used in construction of the endoscopes.

Cleaning and Disinfection (continued)

To avoid damage to the instrument, check the compatibility of reprocessing systems/ processes other than described in this manual with your Welch Allyn representative.

Accessory Sterilization

WARNING: According to current infection control guidelines all accessories that break the mucosal barrier (e.g., biopsy forceps), must be sterilized.

Before sterilizing the accessories, make certain to thoroughly follow the cleaning instructions in the Cleaning Section of this manual. It is up to the user to determine if the sterilization procedures described in this section meet the requirements of the facility.

1. Once the accessories have been cleaned and thoroughly dried, Ethylene Oxide (ETO) Gas sterilization can be performed.
2. Aeration is necessary after the accessories have been subjected to ETO sterilization.

Accessory and Instrument Storage

1. Make sure all water is removed from the instrument and accessories.
2. Store the instrument with the insertion tube and umbilical cable as straight as possible. If coiling is necessary, the insertion tube and umbilical cable should not be wound in more than one loop.
3. Do Not store the instrument in an area exposed to temperature extremes, high humidity, or direct sunlight. The storage area should be dry and clean.
4. Apply silicone oil to the cups of the biopsy forceps to prevent rust.
5. Couple the Shipping/ETO vent to the instrument to balance the internal and external humidity. Before storing, remove all valves, biopsy seals, soaking caps, etc. to allow thorough drying of internal parts.

WARNING: Prior to storage, it is important that no residual water be left within any internal channels/lumens of the instrument or accessories. Thoroughly dry all instrument surfaces to reduce the potential for bacteria colonization during storage.

6. Use optional Welch Allyn wall hanger to store instrument securely (#31035).

NOTE: This equipment contains no hazardous materials and can be disposed after its useful life without any environmental risks.

CAUTION: Avoid crushing or puncturing any video monitor due to risk of CRT implosion. Consult your local waste authority for safe disposal.

Servicing

Prior to returning any instrument for repair to Welch Allyn, the instrument should first undergo appropriate reprocessing/decontamination procedures for the purpose of infection control.

1. All instruments requiring repair should be shipped in the original shipping package with appropriate packing along with comments describing the instrument damage and complaint.
2. A repair/return authorization number, contact name and phone number of the individual responsible for authorizing repairs, as well as shipping address should be included.
3. The ETO/Shipping vent should be attached to the instrument if it will be shipped by air freight.
4. Any accessories potentially related to the scope damage or complaint also should be included with the VideoEndoscope.
5. Soaking caps (if applicable) also should be returned with the VideoEndoscope to check/confirm the integrity of their watertight seal.

NOTE: Instrument repairs should only be performed by an authorized Welch Allyn service facility. Welch Allyn assumes no liability for any patient/user injury, instrument damage or malfunction, or reprocessing failure due to repairs made by unauthorized personnel.

Customer Service Telephone Assistance: 1-800-535-6663

For repairs, ship to:

Welch Allyn Repair Department
4341 State Street Road
Skaneateles Falls, NY 13153

Care and Maintenance Tips

Flexible endoscopes have been an invaluable tool in the medical community's armamentarium to successfully diagnose and treat a wide variety of illnesses in patients for several decades. Perhaps due to their longevity and progressive design changes over the years which have simplified their use, flexible endoscopes have been somewhat taken for granted and have erroneously not been considered highly technological medical devices.

In fact, current generation flexible endoscopes, although easier to clinically use, are more sophisticated than ever. Special reprocessing instructions must be followed to make sure the instruments are patient ready and patient safe. Special care and handling must be exercised and practiced to prevent instrument malfunction and prolong the reliability of the endoscope.

The burden of responsibility to make sure of safe and reliably functioning instruments is left in the hands of the healthcare professionals who actually care for and reprocess flexible endoscopes.

Naturally, equipment manufacturers share this responsibility and tremendous efforts have been spent in designing instruments which could be reprocessed and maintained as easily as possible. However, due to the nature of their use and application, flexible endoscopes must be subjected to special cleaning procedures, followed by a disinfection or sterilization process after each and every patient use.

To highlight and simplify what may appear to some as being complicated maintenance and reprocessing instructions, Welch Allyn strongly recommends that users review the following suggestions and advice on the care and maintenance of your Welch Allyn flexible VideoEndoscope.

These tips, particularly those involving scope reprocessing, should not be construed as "shortcuts" and are not intended as substitute directions for complete instructions found elsewhere in the owner's manual.

- Avoid soaking of the instrument with accessories (e.g., forceps, injection or aspiration needles) or any sharp-edged objects which could inadvertently scratch or cut the distal bending section sheath. (Subsequent flexing back and forth of the rubber sheath could eventually stretch the scratched rubber until a pinhole appears and leak develops.)
- Exposure to a compatible enzymatic detergent is essential to thorough cleaning of all surfaces of the instrument. Rinsing and drying after cleaning is imperative to prevent dilution of the disinfectant/sterilant.
- Do not reuse disposable accessories intended for single patient or one-time use.
- Do not expose the instrument or accessories to harsh chemical solutions. Strictly adhere to exposure times recommended by the manufacturers of compatible solutions.
- Avoid contact of any flexible portion of the instrument with any sharp objects (e.g., bed frames, table top corners, sink drains, accessories hanging in storage cabinets) at any time during the handling, reprocessing, or storage of the instrument.
- Avoid stretching of the bending section rubber sheath at the distal portion of the scope. During mechanical cleaning of the instrument with a dampened gauze, do not use excessive force. A gentle back and forth wiping motion should be sufficient to remove gross debris. Subsequent soaking in an enzymatic detergent will clean the remainder of the debris.
- Disinfectants and sterilants are toxic substances by nature. All residual solution must be thoroughly rinsed and dried prior to each patient use.
- The key to preventing clogged air or water channels/nozzles is to immediately flush the channels upon removal from the patient. This should be followed by soaking with an enzymatic detergent.

Care and Maintenance Tips (continued)

- Avoid attempting to remove or unscrew the instrument's components which should not be removed. Parts such as the distal portion on the end of the bending section and any rubber strain reliefs on either the insertion tube or umbilical cord are essential to the watertight integrity of the instrument. Removal or loosening of these components and subsequent immersion could lead to fluid invasion into the instrument.
- Avoid excessive and/or tight bends in the insertion tube and umbilical cord. Tight curling of these portions of the instrument can result in serious internal damage.
- Never articulate the bending section by applying force directly to the bending section. This can cause serious damage to the internal steering cables.
- If resistance is felt during rotation of the deflection control knobs, do not apply excess force.
- Check for any sharp edges on all surfaces of an automated cleaning/reprocessing unit which may come in contact with an endoscope. Some units may have sharp edged wire mesh filters and baskets or inlet/outlet ports which could damage the instrument.
- The air/water and suction control valves must be screwed down onto their respective cylinders on the instrument's control body to function properly. This is unlike other manufacturer's semi-disposable valves with a rubber base which do not have threads to secure attachment.
- Do NOT overtighten the cap to the water bottle assembly. Overtightening could cause the cap to crack.
- Do NOT introduce air bubbles into the instrument's internal channels during flushing of cleaning and/or disinfecting/sterilizing solutions since the bubbles could interfere in the effectiveness of the disinfection/sterilization process.
- Do NOT store the instrument and accessories in the carrying case since this type of dark, humid, and unventilated environment is conducive to bacteria colonization which increases the risk of cross-contamination.
- Prior to each use, check the condition of all accessories.

  Do NOT use any accessories with kinked or bent flexible shafts.

  Do NOT use forceps with misaligned cups and/or bent needles/spikes.

  Do NOT use aspiration or injection needles which are not retractable or whose sharp tips cannot be protected.

  DO NOT use cleaning brushes without smooth or rounded distal tips.

  Use of any of the above accessories could result in channel damage and costly repairs.
- Verification of the effective concentration of glutaraldehyde (via test strips or similar methods) is recommended to ensure potency of glutaraldehyde to achieve high-level disinfection.
- Instrument repairs should be performed by an authorized Welch Allyn service facility. Welch Allyn assumes no liability for any patient/user injury, instrument damage or malfunction, or reprocessing failure due to repairs made by unauthorized personnel.

Troubleshooting

Symptom	Possible Cause	Solution
No image.	Endoscope not properly plugged in.	Advance endoscope connector terminal into light source until it “clicks” into place.
Image is not clear.	Distal objective lens obscured.	Rinse lens by injecting water through auxiliary water inlet.
	Lenses dirty.	Remove endoscope and clean distal objective lens with cotton swab and alcohol.
	Water damage to lens.	Return to Welch Allyn for evaluation/repair.
Inadequate suction.	Suction valve blocked.	Remove valve, clean valve and housing with a cleaning brush. Lubricate “O” rings with valve lubricant and replace.
	Biopsy seal is worn.	Replace biopsy seal.
	Suction channel blocked.	Call Welch Allyn Service Department for instructions.
	Suction pump not on or tubing disconnected.	Verify good connection between suction pump and endoscope. Turn pump on.
No insufflation.	Air pump not turned on.	Turn air pump on. Test endoscope for air flow.
	Water bottle not connected properly to light source or endo connector plug.	Verify water bottle is properly plugged into light source.
	Air nozzle blocked.	Soak tip of endoscope in warm soapy water for 2-3 minutes. Gently brush with air/water nozzle cleaning brush. Gently inject warm water through the endoscope by depressing the air/water feed valve. If the nozzle remains blocked, contact Welch Allyn Customer Service.
	Water bottle cap not secured tightly.	Tighten cap.
Cannot irrigate.	Water bottle empty.	Fill water bottle to fill line.
	Water bottle not connected properly to light source or endo connector plug.	Verify water bottle is properly plugged into light source.
	Water bottle cap not secured tightly.	Tighten cap.

Troubleshooting (continued)

Symptom	Possible Cause	Solution
Distal tip will not return to 'neutral' position.	Deflection lock lever either partially or fully engaged.	Rotate deflection lock lever until distal tip can freely return to 'neutral' position.
Suction or Air/Water valve sticks.	Dirty valve stem.	Remove valve; clean valve and housing with cotton swab and alcohol; lubricate "O" rings with valve lubricant and replace.
	Bad "O" rings.	Replace "O" rings.
Biopsy seal "spitting" or leaking.	Biopsy seal is worn.	Replace biopsy seal.
Insufficient articulation of tip.	Loose articulation knob.	Return endoscope to Welch Allyn for adjustment.
	Degree of articulation is less than specified.	Return endoscope to Welch Allyn for adjustment.
Inadequate illumination.	Light source not turned on.	Turn on power to light source.
	Damage to light transmitting fibers.	Return endoscope to Welch Allyn for evaluation/repair.
Light source not working.	Not plugged into electrical outlet.	Plug light source into 120 volt grounded outlet.
	Lamps burned out.	Replace lamps according to instructions.
	Fuse is blown.	Call Welch Allyn Service Department.
	Lamp access plate not properly re-installed.	
No illumination.		Endoscope connector plug not properly engaged.
Electronic Function Controls do not operate.	RS-232 cable not connected between VLX-20 Light Source and video printer.	Connect RS-232 cable.
	Video printer not in proper signal input mode.	Adjust video printer until proper input mode is selected (Composite, S-Video, RGB).
	Printer not adjusted to proper baud rate.	Set printer to 9600 baud.

Welch Allyn®

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